REMARKS

Applicant notes with appreciation the acceptance of request for continued examination filed on 1/29/2007 and the thoroughness of the Office Action of 18 April 2007. This amendment is submitted to be fully responsive thereto. By way of this amendment, claims 4-6, 30-33, 37-39, 41, and 42 have been canceled; claims 1, 7, 29, 34, 36, and 40 have been amended to recite with greater clarity that the inventive method is directed to treating a subject having neurotrauma or neuronal injury with a therapeutically effective amount of choline magnesium trisalicylate. Support for this amendment is found in the claims as originally filed. As such, it is submitted that no new matter has been added by way of this amendment.

Claims 1, 7, 29, 34-36, and 40 are the claims pending and currently under examination in this case. Claims 2-3, 8-28, and 42 are newly canceled. Claims 1, 7, 29, 34-36, and 40 stand rejected under 35 U.S.C. §103(a) over Grilli et al. (WO 98/20864) in view of Bakhshi et al. (Journal of Neuro Oncology, 26, 133-9), and Myseros et al. (The rationale for glutamate antagonists in the treatment of traumatic brain injury, Ann NY Acad Sci, 1995, 765:262-271).

Remarks Directed to Rejection of Claims 1, 7, 29, 34-36, and 40 Under 35 U.S.C. §103(a) over Grilli et al. in view of Bakhshi et al. and Myseros et al.

It is stated on page 2-3 of the Paper No. 20070416 that "the 103(a) rejections of the last office action are maintained" because "Grilli et al. teaches, on page 3....that inflammatory processes contribute to the pathology of neurodegenerative diseases..." and because "the NSAIDs still possess anti-inflammatory properties inherently."

It is stated on page 6 of the Paper No. 20070416 that "one would have been motivated to administer the composition of Grilli et al.... because of an expectation of success in treating neuronal damage associated with Alzheimer's, as taught by Grilli et al. and in treating neurotrauma as taught by Myseros et al...."

By way of this amendment, the pending claims have been amended to recite the specific use of choline magnesium trisalicylate in treating neurotrauma.

At the outset, Applicant agrees that Grilli et al. lacks a "specific teaching of the treatment of neurotrauma associated with traumatic brain injury (i.e., traumatic brain trauma and diffuse axonal injury associated with such)" (page 4 of the Paper No. 20070416).

It is respectfully submitted that Myseros et al. fails to bolster the limitation of Grilli et al. because the teaching of Myseros et al. provides, at most, an "motivation to try" with regarding to specific therapeutic intervention suitable for treating neurotrauma. The law is settled that "motivation to try" is an insufficient basis to maintain a obviousness-type rejection under 35 U.S.C. 103(a).

Contrary to neurodegenerative disease such as Alzheimer's diseases as disclosed in Grilli et al. where the etiology of the disease is rather genetic or hereditary in nature, neurotrauma or neuronal injury involves many contributing factors that are external to the brain. These external factors include impact contact with a surface, and mechanical dislocation. These factors induce acute tissue loss and bleeding. Although Myseros et al. disclose mechanisms of traumatic brain injury and point out in particular the involvement of excitatory amino acids (page 5 of the Paper No. 20070416), Myseros et al. does not provide any suggestion as to a particular treatment directing to neurotrauma or neuronal injury. In fact, the teaching of Myseros et al. provides, at most, a motivation to try based on the "rationale" so provided. However, a prior art suggestion for virtually endless experimentation is not a case of prima facie obviousness. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1989). It is evident in Myseros et al. that at least three different mechanisms are said to might have been involved in mediating head injuries (fifth paragraph, page 268), however

no specific instruction is provided as to what technique can be employed to detect a particular mechanism, let alone a proper treatment thereof.

Furthermore, Applicant agrees that Grilli et al. in view of Bakhshi et al. and Myseros et al. "lack a teaching of choline magnesium trisalicylate" (paragraph two on page 7 of the Paper No. 20070416).

It is noted that choline magnesium trisalicylate significantly differs from other NSAIDs such as sodium salicylate or salicylamide in various aspects. In comparison to sodium salicylate or salicylamide where either contains a single salicylate ion, choline magnesium trisalicylate releases three salicylate ions when dissolved in water. As a result, choline magnesium trisalicylate offers prolongation of salicylate half-life and a non-linear increase in plasma salicylate level. Additional, magnesium has neurotherapeutic activity and as such the simultaneous delivery of salicylate and magnesium affords a synergistic effect. Moreover, unlike other NSAIDs such as sodium salicylate or salicylamide, choline magnesium trisalicyalte does not affect platelet aggregation. Therefore, since choline magnesium trisalicylate differs from sodium salicylate or salicylamide both structurally and functionally, it is submitted that specific teachings regarding sodium salicylate or salicylamide provided by Grilli et al. do not render obvious pending claims which relates specifically to choline magnesium trisalicylate administration. Because the recitation of choline magnesium trisalicylate as recited in base claims 1, 29 36 of the instant invention is not an obvious variation of traditional salicylates taught in the prior art, it is submitted that this recitation found in the pending independent claims is entitled to patentable weight.

In view of the above remarks, reconsideration and the withdrawal of the rejection of claims 1, 29, 36 and dependent claims thereof under 35 U.S.C. §103(a) over Grilli et al. in view of Bakhshi et

al. and further in view of Myseros et al. is solicited. In the event that this rejection is maintained, it is respectfully requested that obviousness rejections to the use of choline magnesium trisalicylate for treating neurotrauma or neuronal injury be stated with greater clarity.

Remarks Directed to Rejection of Claim 42 Under 35 U.S.C. §103(a) Over Grilli et al. in View of Bakhshi et al. and Myseros et al. and Further in View of McGeer et al.

This rejection is moot in light of the cancellation of claim 42.

Summary

Claims 1, 7, 29, 34-36, and 40 are the claims pending in this application. Each claim is believed to be in proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims is requested. Should the Examiner find to the contrary, he is respectfully requested to contact the undersigned attorney in charge of this application to resolve any remaining issues.

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Respectfully submitted,

/Avery N. Goldstein/

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